Full Text PA-97-058

RESEARCH ON LOW BACK PAIN AND COMMON SPINAL DISORDERS

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PURPOSE

This initiative invites applications directed to the study of the pathogenesis, epidemiology, prevention, and treatment of three common causes of low back pain: (1) herniated nucleus pulposus; (2) spinal stenosis; and (3) idiopathic low back pain.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This PA, Low Back Pain, is related to the priority area of chronic disabling conditions. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0 or Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402- 9325 (telephone 202-512-1800).

ELIGIBILITY REQUIREMENTS

Applications may be submitted by foreign and domestic, for-profit and non-profit organizations, public and private, such as universities, colleges, hospitals, laboratories, units of State and local governments, and eligible agencies of the Federal government. Foreign institutions or organizations in foreign countries are not eligible for First Independent Research Support and Transition (R29) awards. Applications from for minority individuals, women, and persons with disabilities are encouraged.

MECHANISM OF SUPPORT

The support mechanisms for grants in this area will be the individual investigator-initiated research grant (R01) and the First Independent Research Support and Transition (FIRST) Award (R29).

Applicants or collaborators from institutions that have a General Clinical Research Center (GCRC) funded by the National Center for Research Resources may wish to identify the GCRC as a resource for conducting the proposed research. If so, a letter of agreement from the GCRC program director should be included with the application.

RESEARCH OBJECTIVES

Background

Low back pain continues to be a significant public health problem. Seventy to 85% of all people have back pain at some time in life, with the annual prevalence of back pain ranging from 15-45%. Back pain is the most frequent cause of activity limitation in people below 45 years and is a common reason for visiting a health care provider. Symptoms are most common in middle-aged adults, with back pain equally common in men and women; however, back pain secondary to disc disorders is more common in men. Reported rates of low back pain are generally higher for Whites than Blacks or other racial groups.

The recurrence rate of low back pain is very high. Indeed, recurrences appear to be part of the natural history. One year recurrence rates have been reported ranging from 20-44%. Lifetime recurrences of 85% have been reported. Fortunately, most patients with back pain recover quickly and without residual functional loss. Typically, 60-70% recover by 6 weeks and 80-90% by 12 weeks. After 12 weeks, further recovery is slow.

Each year, about 2% of the work force have back injuries covered by workman's compensation. The total annual direct cost of treating this subgroup of low back pain patients rose from $4.6 billion in 1977 to $11.4 billion in 1994. Typically, 25% or fewer of low back cases are responsible for 75% or more of the cost.

There continues to be great variability in health care service utilization for low back pain. From 1979 to 1987, U.S. rates of back surgery increased 49-55%, while the rate of non-surgical hospitalization decreased 33%. Marked geographic variation in the rate of back surgery (twice as high in the South as compared to the Northeast) has been reported. The increase in surgical rates was especially marked for fusions, which increased 100% from 1979 to 1990. In addition, there is marked international variation in rates of back surgery. A recent study comparing the rates of back surgery in thirteen countries and provinces revealed that the rate of back surgery in the U.S. was 40% higher than in any other country or province. These differences in surgical rates were not felt to be due to underlying differences in the prevalence of low back pain. Complicating this variability in service utilization is the reality that only a small number of the commonly used non- operative and operative treatments have been scientifically validated for their effectiveness/outcomes.

This PA is an outgrowth of a workshop sponsored by the NIAMS and the American Academy of Orthopaedic Surgeons on "New Horizons in Low Back Pain" in November 1995. A primary objective of the workshop was to develop suggestions for future research directions in the pathogenesis and treatment of common spinal disorders. A more detailed description of the proceedings and suggested research topics is available in Low Back Pain: A Scientific and Clinical Overview, edited by J. N. Weinstein and S. L. Gordon, American Academy of Orthopae dic Surgeons, Chicago, 1996.

Scope

Through the use of this PA, the NIAMS, the NICHD, the NINDS, and the NIOSH anticipate the receipt of a broad range of basic science studies to better understand the pathogenesis, epidemiology, and prevention of common low back disorders. In addition, we encourage the development of patient oriented studies that address: (1) the efficacy of current physical examination methods and diagnostic imaging studies; and (2) the apparent lack of scientific validation of efficacy/effectiveness/ outcomes of commonly used non-operative and operative treatments for three of the most common low back disorders: herniated nucleus pulposus (ruptured disc), spinal stenosis, and idiopathic low back pain (low back pain of unknown etiology).

The following are examples of research topics that are appropriate for this PA; however, they are not to be considered as exclusive or limiting:

o Studies of the natural history of these common low back conditions/disorders.

o The roles of cytokines and other inflammatory mediators in the development and maintenance of acute and chronic pain, and in nerve root injury.

o A better understanding of the neurophysiology of low back pain in these disorders.

o Studies to test the hypothesis that clinical spinal instability relates the spinal derangement or loss of stability to pain. Identify the important factor(s) associated with clinical instability in low back pain.

o A better understanding of the contribution of proteoglycans, and/or their degradation products, as a cause of low back pain.

o A better understanding of the material properties of the annulus fibrosis, nucleus pulposus, and cartilage end-plate loading modes.

o Develop and/or validate model(s) that mimic the clinical diagnosis of spinal stenosis. It is recommended that such models induce compression by narrowing the spinal canal, rather than by the introduction of foreign material.

o Study of the pathophysiology of low back pain. This should include study of normal physiologic aging of the spine and its related soft tissues, and how this may relate to the pathophysiology of low back pain.

o Studies relating deconditioning/loss of muscle strength and/or coordination to the onset and/or prolongation of low back pain.

o Studies to further clarify the role of diagnostic testing in patients with low back pain. This includes validation of physical examination techniques, electrodiagnostic techniques (EMG-NCV), and the timing and effectiveness of commonly used imaging studies (e.g., routine xrays, CT scan, MRI).

o Prospective, randomized, controlled, clinical trials of the more common non-operative and operative treatments currently in use for these common low back disorders.

o Study of the role of occupational factors in the development, prognosis, and recovery from low back pain. Occupational factors include, but are not limited to, biomechanical stressors, muscle fatigue, and work organizational factors.

o Studies investigating the incidence, diagnosis, treatment, and prevention of low back pain in persons with pre-existing severe disability (e.g., brain injury, stroke, spinal cord injury, amputation, cerebral palsy).

Applications are encouraged in any scientifically meritorious research area related to low back pain in these spinal disorders. Research applications are encouraged from all basic science disciplines pertinent to this area, as well as the medical specialties providing health care for these patients, including, but not limited to: orthopaedic and neurosurgeons, occupational medicine physicians, internists and family practitioners, rheumatologists, physiatrists, chiropractic and osteopathic practitioners, and allied health providers.

INCLUSION OF WOMEN AND MINORITIES IN RESEARCH INVOLVING HUMAN SUBJECTS

It is the policy of the NIH that women and members of minority groups and their subpopulations must be included in all NIH supported biomedical and behavioral research projects involving human subjects, unless a clear and compelling rationale and justification is provided that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. This policy results from the NIH Revitalization Act of 1993 (Section 492B of Public Law 103-43).

All investigators proposing research involving human subjects should read the "NIH Guidelines for Inclusion of Women and Minorities as Subjects in Clinical Research," which have been published in the Federal Register of March 28,1994 (FR 59 14508-14513), and reprinted in the NIH Guide for Grants and Contract, Volume 23, Number 11, March 18, 1994.

APPLICATION PROCEDURES

Applications are to be submitted on the grant application form PHS 398 (rev. 5/95) and will be accepted at the standard application deadlines as indicated in the application kit. Applications

kits are available at most institutional offices of sponsored research and may be obtained from the Division of Extramural Outreach and Information Resources, National Institutes of Health, 6701 Rockledge Drive, MSC 7910, Bethesda, MD 20892-7910, telephone 301/435-0714, email: ASKNIH@odrockm1.od.nih.gov. The title and number of the program announcement must be typed in Section 2 on the face page of the application.

Applications for the FIRST Award (R29) must include at least three sealed letters of reference attached to the face page of the original application. FIRST Award (R29) applications submitted without the required number of reference letters will be considered incomplete and will be returned without review.

The completed original application and five legible copies must be sent or delivered to:

DIVISION OF RESEARCH GRANTS
NATIONAL INSTITUTES OF HEALTH
6701 ROCKLEDGE DRIVE, ROOM 1040 - MSC 7710
BETHESDA, MD 20892-7710
BETHESDA, MD 20817 (for express/courier service)

REVIEW CONSIDERATIONS

Upon receipt, applications will be reviewed for completeness by the DRG. Incomplete applications will be returned to the applicant without further consideration.

Applications will be assigned on the basis of established Public Health Service referral guidelines. Applications will be reviewed for scientific and technical merit by an appropriate peer review group convened in accordance with NIH peer review procedures. As part of the initial merit review, all applications will receive a written critique and may undergo a process in which only those applications deemed to have the highest scientific merit, generally the top half of all applications under review, will be discussed, assigned a priority score, and receive a second level review by the appropriate national advisory council or board.

Review Criteria

o Scientific, technical, or medical significance and originality of proposed research;

o Appropriateness and adequacy of the experimental approach and methodology proposed to carry out the research;

o Qualifications and research experience of the Principal Investigator and staff, particularly, but not exclusively, in the area of the proposed research;

o Availability of the resources necessary to perform the research;

o Appropriateness of the proposed budget and duration in relation to the proposed research; and

o Adequacy of plans to include both genders and minorities and their subgroups as appropriate for the scientific goals of the research. Plans for the recruitment and retention of subjects will also be evaluated.

The Initial Review Group will also examine the provisions for the protection of human subjects and animal welfare and the safety of the research environment.

AWARD CRITERIA

Applications will compete for available funds with all other approved applications assigned to NIAMS and NINDS. The following will be considered in making funding decisions:

o Quality of the proposed project as determined by peer review
o Availability of funds
o Program relevance and balance among research areas of the announcement

INQUIRIES

Written and telephone inquiries are encouraged. The opportunity to clarify any issues or questions from potential applicants is welcome.

For scientific programmatic inquiries contact:

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Direct inquiries regarding fiscal matters to:

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AUTHORITY AND REGULATIONS

Awards made in this program are described in the Catalog of Federal Domestic Assistance No. 93.846, Arthritis, Musculoskeletal and Skin Diseases Research, the National Institute of Arthritis and Musculoskeletal and Skin Diseases, No. 98.853, Clinical Research Related to Neurological Disorders, and No. 93.854, Biological Basis Research in the Neurosciences, the National Institute of Neurological Disorders and Stroke. Awards will be made under the authority of the Public Health Service Act, Title III, Section 301 (Public Law 410, 78th Congress, as amended, 42 USC 241) and administered under PHS grant policies and Federal regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

The PHS strongly encourages all grant and contract recipients to provide a smoke-free workplace and promote the non-use of all tobacco products. In addition, Public Law 103-227, the Pro-Children Act of 1994, prohibits smoking in certain facilities (or in some cases, any portion of a facility) in which regular or routine education, library, day care, health care or early childhood development services are provided to children. This is consistent with the PHS mission to protect and advance the physical and mental health of the American people.

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